

## **REMARKS**

In the Office Action of April 19, 2005, claims 1-4, 6-10, 12-17, and 19-20 were rejected as being anticipated by the document "Selective Laser Sintering Streamlines Prosthesis Design" Machine Design, Penton, Inc., Cleveland, U.S., vol. 65, no. 3, February 12, 1993, page 77, ISSN:00249114 (hereafter "Machine Design"). Additionally, claims 15 and 16 were rejected as being anticipated by U.S. Pat. No. 5,432,703 (hereinafter "Clynch"). Still further, claim 15 and 16 were rejected as being anticipated by U.S. Pat. No. 5,376,132 issued to Caspers (hereinafter "Caspers"). Finally, claims 5, 11, and 18 were rejected as being obvious over Machine Design in view of Clynch.

Applicant has herein cancelled claims 1, 2, 4, 7, and 8. Additionally, Applicant has amended each of claims 3, 5, 6, and 9 into independent form. Still further, Applicant has amended claim 10 to correct typographical errors. Finally, Applicant submits the ensuing remarks in support of the allowability of the present claims.

### **Claim 3 Is Neither Anticipated By Machine Design Nor Obvious In View Of The Prior Art**

Claim 3 requires, among other things, the step of forming the socket out of physical material to occur in a manner such that the digitally controlled layered manufacturing technique automatically forms an access opening in the socket that extends into the cavity from the exterior surface. As claimed, this access opening must be something other than the opening into the cavity that extends through the non-planar perimeter surface (i.e., the opening through which a residual limb passes after the prosthetic limb has been attached to the residual limb). Moreover, claim 3 requires a step of accessing the cavity of the socket through the access opening after the

prosthetic limb has been attached to the residual limb.

Machine Design does not disclose any step of forming the socket out of physical material to occur in a manner such that the digitally controlled layered manufacturing technique automatically forms an access opening in the socket that extends into the cavity from the exterior surface and therefore can not anticipate claim 3. Moreover, the prior art of record does not disclose or suggest any method that includes forming a socket out of physical material in a manner such that the digitally controlled layered manufacturing technique automatically forms an access opening in the socket that extends into the cavity from the exterior surface of the socket.

Because the prior art fails to disclose or suggest each and every limitation of claim 3, claim 3 is neither anticipated by nor obvious in view of the prior art. As such, Applicant requests that the rejection of claim 3 be reconsidered and withdrawn.

#### Claim 5 Is Not Obvious Over Machine Design In View OF Clynch

Claim 5 requires, among other things, the step of positioning at least one artifact, which has a non-planer three-dimensional contour, adjacent the residual limb, and requires the scanning to occur in a manner creating a plurality of digital representations of surface contours that are dependent on the three-dimensional surface contour of the artifact. Furthermore, claim 5 requires aligning the plurality of digital representations of surface contours relative to each other by aligning portions of the plurality of digital representations of surface contours that are dependent on the artifact.

The Office states that Clynch teaches a step of “positioning at least one artifact adjacent the residual limb prior to electronically scanning the exterior surface contour of

the liner for the purpose of holding the patient in a standing position” and that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to hold the patient in a standing position.” However, regardless of whether or not Clynch teaches such steps, Clynch does not teach any method in which the scanning occurs in a manner creating a plurality of digital representations of surface contours that are dependent on a non-planer surface contour of any artifact, and in which the plurality of digital representations of surface contours are aligned relative to each other by aligning portions of the plurality of digital representations of surface contours that are dependent on the three-dimensional surface contour of the artifact.

Clynch discloses placing dots on special stretchable stocking used for scanning a residual limb. Clynch, col. 6, lines 45-50. However, the dots do not have a non-planer three-dimensional surface contour. Moreover, the dots in the Clynch process create gaps or VOID points in the data collected by the laser scanning described in Clynch. Clynch, col. 7, lines 5-6. The methods disclosed in Clynch in no way teach the creation of any plurality of digital representations of surface contours that are dependent on a non-planer surface contour of any artifact. Moreover, Clynch does not disclose the creation of the a plurality of digital representations of surface contours that must be aligned because Clynch teaches using a laser scanner that revolves 360 degrees around a residual limb to create a single contour. Thus Clynch does not teach or suggest any step of aligning a plurality of digital representations of surface contours with each other.

In contrast, the use of an artifact in accordance with claim 5 of the present application facilitates alignment of digital representations of surface contours by

providing abrupt or particular surface contours that are easily identifiable by surface contour analysis software (unlike most portions of a typical surface contour of residual limb). Thus, the use of an artifact in accordance with claim 5 would not be obvious in view of either Clynych, Machine Design, or the combination thereof.

For the forgoing reasons, applicant submits that claim 5 is not obvious in view of the prior art. As such, Applicant requests that the rejection of claim 5 be reconsidered and withdrawn.

Claim 6 Is Neither Anticipated By Machine Design Nor Obvious In View Of The Prior Art

Claim 6 requires, among other things, a step of generating a digital representation of the three-dimensional surface contour that comprises electronically scanning the portion of the residual limb with a liner positioned on the residual limb. Claim 6 also requires a step of attaching the prosthetic limb to the residual limb by positioning the residual limb with the liner positioned thereon at least partially into the cavity of the socket.

Caspers pertains to a method of making a liner and does not disclose or suggest any method of scanning a liner to create a socket. Clynych discloses scanning a special "stocking" to create a socket. The special socket of Clynych is adapted to allow a patient to support a substantial amount of his or her body weight in the stocking so as to provide a contour for scanning that differs from the natural contour of the person's residual limb. Clynych, col. 5, lines 60-67. Likewise, the contour scanned in the method of Clynych would differ from the contour of a liner placed on the residual limb as is utilized in connection with the method of claim 6 of the present application. While

Applicant agrees with the Office Action that the contour of the liner on the residual limb will be dependent upon the residual limb, Applicant does not agree that the contour of the liner will be the same as that of the residual limb. When the liner is placed on a residual limb, it necessarily alters the contour of the residual limb because it creates a radially inward pressure of the residual limb which distorts the soft tissue of the residual limb. For the same reason, the contour of the liner on a residual limb would differ from the contour of the stocking disclosed in Clynych on the same residual limb because of the weight bearing step disclosed in Clynych and because of the physical differences between a liner and a stocking.

For these reasons, the prior art does not disclose or suggest electronically scanning a portion of the residual limb with a liner positioned on the residual limb, as is required by claim 6. Moreover, the prior art does not teach or suggest attaching a prosthetic limb to a person's residual limb by positioning the residual limb with the scanned liner thereon at least partially into the cavity of the socket, as is required by claim 6. Moreover, it would be disadvantageous to utilize the stocking of Clynych to attach a prosthetic limb to the person's residual limb because there is no means for connecting the stocking to the socket and the metal ring at the top end of the socket would interfere with the normal use of the prosthetic device. For these reasons, it would not be obvious, nor would it be advantageous, to modify the method taught by Clynych by utilizing the stocking in place of a liner or to utilize a liner in place of the stocking.

Because the prior art fails to suggest or teach a method that comprises electronically scanning the portion of the residual limb with a liner positioned on the residual limb in combination with a step of attaching the prosthetic limb to the residual

limb by positioning the residual limb with the liner positioned thereon at least partially into the cavity of the socket, claim 6 is not anticipated by nor obvious in view of the prior art. As such, Applicant respectfully requests the rejection of claim 6 be reconsidered and withdrawn.

Claim 9 Is Neither Anticipated By Machine Design Nor Obvious In View Of The Prior Art

Claim 9 requires, among other things, a step of forming a socket out of physical material using the digitally controlled layered manufacturing technique that comprises forming a socket wall with a non-linear passageway therein using the digitally controlled layered manufacturing technique, and a step of routing an electrically conductive wire within the passageway of the socket.

The Office Action does not address these limitations nor are they disclosed in Machine Design. It is many times more difficult to form non-linear passageways in most structures than it is to form linear passageways in such structures. Thus, with sockets formed by means other than digitally controlled layered manufacturing techniques, it would be disadvantageous to form non-linear passageways in walls of such sockets. Moreover, simply because it is relatively easy to form non-linear passageways in socket walls using digitally controlled layered manufacturing techniques does not negate the nonobviousness of doing such, nor are the advantages of doing such obvious.

Because the prior art fails to suggest or teach a method that comprises a step of forming a socket out of physical material using the digitally controlled layered manufacturing technique that comprises forming a socket wall with a non-linear passageway therein using the digitally controlled layered manufacturing technique, and

a step of routing an electrically conductive wire within the passageway of the socket, claim 9 is not anticipated by nor obvious in view of the prior art. As such, Applicant respectfully requests the rejection of claim 9 be reconsidered and withdrawn.

Claim 10 Is Neither Anticipated By Machine Design Nor Obvious In View Of The Prior Art

Claim 10 requires, among other things, steps of positioning a liner on at least a portion of the residual limb, electronically scanning at least a portion of the liner when the liner is positioned on the residual limb to generate a digital representation of a three-dimensional surface contour that is dependent on a physical three-dimensional surface contour of the liner, generating a digital representation of a socket which has a cavity defined by an interior surface that is defined at least partially by the digital representation of the three-dimensional contour, using a digitally controlled layered manufacturing technique driven by the digital representation of the socket to form the interior surface of the socket out of physical material; and attaching the socket of the prosthetic limb to the residual limb by positioning the residual limb with the liner positioned thereon at least partially into the cavity of the socket.

For the reasons discussed above in reference to claim 6, the prior art fails to suggest or teach a method that comprises electronically scanning the portion of the residual limb with a liner positioned on the residual limb in combination with a step of attaching the prosthetic limb to the residual limb by positioning the residual limb with the liner positioned thereon at least partially into the cavity of the socket. For these reasons

alone, claim 10 is not anticipated by nor obvious in view of the prior art. As such, Applicant respectfully requests the rejection of claim 10 be reconsidered and withdrawn.

Claim 10 also requires steps of marking the liner in a manner indicating a preferred contour and location of a non-planer terminal edge of the socket when the liner is positioned on the residual limb, electronically scanning the liner in a manner such that the contour and location of the non-planer terminal edge of the socket that has been marked on the liner is identifiable in the digital representation of the three-dimensional surface contour, generating the digital representation of the socket in a manner such that the digital representation of the socket has a perimeter surface that terminates the cavity and that is dependent upon the contour and location of the non-planer terminal edge of the socket that is identifiable in the digital representation of the three-dimensional surface contour, and using a digitally controlled layered manufacturing technique driven by the digital representation of the socket to form the perimeter surface of the socket out of physical material.

While Clynych discloses marking a stocking with non-reflective dots for reference in an electronically scanned digital representation of a residual limb, it would not be obvious in view of Clynych to mark a liner with a preferred contour and location of where a perimeter edge of the socket should be formed. One reason this would not be obvious is that the purpose of the electronic scanning disclosed in Clynych is to form a positive mold of the residual limb, not a socket, using digitally controlled milling techniques. Clynych, col. 5, lines 30-35. After this is done, a socket is formed using conventional techniques. Thus, the perimeter edge of the socket is not formed by any

digitally controlled manufacturing technique and therefore there would be no reason to include a representation of the perimeter edge in any digital geometry.

For the foregoing reason, the prior art fails to teach or suggest the step of electronically scanning the liner in a manner such that the contour and location of the non-planer terminal edge of the socket that has been marked on the liner is identifiable in the digital representation of the three-dimensional surface contour, as is required by claim 10. For this additional reason, claim 10 is not anticipated by nor obvious in view of the prior art.

In view of the forging, Applicant respectfully requests the rejection of claim 10 be reconsidered and withdrawn.

#### Claim 11 Is Not Obvious In View Of The Prior Art

Claim 11 is dependent upon claim 10 and therefore includes each and every limitation of claim 10. As such, for the reasons that claim 10 is not obvious in view of the prior art as set forth above, claim 11 is not obvious in view of the prior art.

Additionally, Claim 11 further requires steps of positioning at least one artifact adjacent the residual limb and aligning a plurality of digital representations of surface contours relative to each other by aligning portions of the plurality of digital representations of surface contours that are dependent on the artifact. These steps are similar to those discussed above in reference to claim 5. As such, claim 11 is not obvious in view of the prior art for the additional reasons set forth above in reference to claim 5.

In view of the forging, Applicant respectfully requests the rejection of claim 11 be reconsidered and withdrawn.

Claims 12 and 13 Are Neither Anticipated By Nor Obvious In View Of The Prior Art

Claims 12 and 13 are each dependent upon claim 10 and therefore include each and every limitation of claim 10. As such, for the reasons that claim 10 is not obvious in view of the prior art as set forth above, claims 12 and 13 are not obvious in view of the prior art and therefore Applicant respectfully requests the rejections of claims 12 and 13 be reconsidered and withdrawn.

Claim 14 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 14 is dependent upon claim 10 and therefore includes each and every limitation of claim 10. As such, for the reasons that claim 10 is not obvious in view of the prior art as set forth above, claim 14 is not obvious in view of the prior art.

Additionally, Claim 14 further requires the step of generating the digital representation of the socket to comprise generating the digital representation of the socket in a manner such that a passageway having a non-linear trajectory is formed between the interior and exterior surfaces of the socket and extends transversely to the thickness of the socket wall, and requires the step of forming the socket out of physical material using the digitally controlled layered manufacturing technique to comprise using the digitally controlled layered manufacturing technique to form the passageway of the socket. Still further, claim 14 requires the additional step of routing an electrically conductive wire within the passageway of the socket. These steps are similar to those

discussed above in reference to claim 9. As such, claim 14 is neither anticipated by nor obvious in view of the prior art for the additional reasons set forth above in reference to claim 9.

In view of the forging, Applicant respectfully requests the rejection of claim 14 be reconsidered and withdrawn.

#### Claims 15 Is Neither Anticipated By Nor Obvious In View of the Prior Art

Claim 15 requires, among other things, the forming of the socket to occur without a process of intentionally rectifying the contour of the interior surface for the purpose of altering the bearing characteristics between the socket and the liner.

Clynch also fails to disclose any forming of a socket that occurs without a process of intentionally rectifying the contour of the interior surface for the purpose of altering the bearing characteristics between the socket and a liner. In fact, Clynch teaches that such altering is necessary.<sup>1</sup> To this end, most of the description in Clynch and each of the claims of Clynch are directed to processes of intentionally rectifying the contour of the interior surface of a socket for the purpose of altering bearing characteristics. Thus, Clynch not only fails to disclose or suggest the method of claim 15, but also specifically and explicitly teaches away from the method of claim 15.

Likewise Caspers also teaches processes of intentionally rectifying the contour of the interior surface of a socket for the purpose of altering bearing characteristics.

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<sup>1</sup> Clynch recites "... modification is required in the interior surface of the socket to take into account which parts of the residual limb are to carry weight, [and] which are to be relatively free of pressure.." Column 5, lines 22-25.

Caspers, Col. 6, lines 38-44. Still further, Machine Design teaches that the digitized data is “manipulated as necessary to improve fit, comfort, and stability of the prosthetic socket.” Machine Design, col. 2, lines 9-11 (emphasis added).

For the above-mentioned reasons, the prior art fails to disclose or suggest the formation of a socket without a process of intentionally rectifying the contour of the interior surface for the purpose of altering the bearing characteristics between the socket and the liner, as is required by claim 15. Moreover the prior art actually teaches away from forming a socket without a process of intentionally rectifying the contour of the interior surface for the purpose of altering the bearing characteristics between the socket and the liner. For these reasons, claim 15 is neither anticipated by nor obvious in view of the prior art.

In view of the forging, Applicant respectfully requests the rejection of claim 15 be reconsidered and withdrawn

#### Claim 16 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 16 is dependent upon claim 15 and therefore includes each and every limitation of claim 15. As such, for the reasons that claim 15 is neither anticipated by nor obvious in view of the prior art as set forth above, claim 16 is neither anticipated by nor obvious in view of the prior art and therefore Applicant respectfully requests the rejections of claim 16 be reconsidered and withdrawn.

#### Claim 17 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 17 is dependent upon claim 15 and therefore includes each and every

limitation of claim 15. As such, for the reasons that claim 15 is neither anticipated by nor obvious in view of the prior art as set forth above, claim 17 is neither anticipated by nor obvious in view of the prior art.

Additionally, claim 17 further requires the step of forming the socket to comprise electronically scanning the exterior surface contour of the liner to generate a digital representation of the socket that is dependent upon at least a portion of the exterior surface contour of the liner, and to comprise using a digitally controlled layered manufacturing technique driven by the digital representation of the socket to form the socket out of physical material. These steps are similar to those discussed above in reference to claim 6. As such, claim 17 is neither anticipated by nor obvious in view of the prior art for the additional reasons set forth above in reference to claim 6.

In view of the forging, Applicant respectfully requests the rejection of claim 17 be reconsidered and withdrawn.

#### Claim 18 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 18 is dependent upon each of claims 15 and 17 and therefore includes each and every limitation of claims 15 and 17. As such, for the reasons that claim 17 is not obvious in view of the prior art as set forth above, claim 18 is not obvious in view of the prior art.

Additionally, claim 18 further requires the steps of positioning at least one artifact adjacent the residual limb and aligning a plurality of digital representations of surface contours relative to each other by aligning portions of the plurality of digital representations of surface contours that are dependent on the artifact. These steps are

similar to those discussed above in reference to claim 5. As such, claim 18 is not obvious in view of the prior art for the additional reasons set forth above in reference to claim 5.

In view of the forging, Applicant respectfully requests the rejection of claim 18 be reconsidered and withdrawn.

Claim 19 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 19 is dependent upon claims 15 and 17 and therefore includes each and every limitation of claims 15 and 17. As such, for the reasons that claim 17 is neither anticipated by nor obvious in view of the prior art as set forth above, claim 19 is neither anticipated by nor obvious in view of the prior art and therefore Applicant respectfully requests the rejections of claim 19 be reconsidered and withdrawn.

Claim 20 Is Neither Anticipated By Nor Obvious In View Of The Prior Art

Claim 20 is dependent upon each of claims 15 and 17 and therefore includes each and every limitation of claims 15 and 17. As such, for the reasons that claim 17 is not obvious in view of the prior art as set forth above, claim 20 is not obvious in view of the prior art.

Additionally, claim 20 further requires the step of generating the digital representation of the socket to comprise generating the digital representation of the socket in a manner such that a passageway having a non-linear trajectory is formed between the interior and exterior surfaces of the socket and extends transversely to the thickness of the socket wall, and requires the step of forming the socket out of physical

material using the digitally controlled layered manufacturing technique to comprise using the digitally controlled layered manufacturing technique to form the passageway of the socket. Still further, claim 20 requires the additional step of routing an electrically conductive wire within the passageway of the socket. These steps are similar to those discussed above in reference to claim 9. As such, claim 20 is neither anticipated by nor obvious in view of the prior art for the additional reasons set forth above in reference to claim 9.

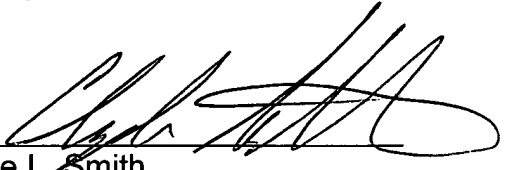
In view of the forging, Applicant respectfully requests the rejection of claim 20 be reconsidered and withdrawn.

#### **CONCLUSION**

In view of the above, Applicant submits that this application is in condition for allowance and notification of such is respectfully requested.

Respectfully submitted,  
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